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THIS STORY IS FROM AUGUST 31, 2013

Panel raps government over clinical trials, lapses

Rupali Mukherjee (Https://Timesofindia.Indiatimes.Com/Toireporter/Author-Rupali-Mukherjee-18424.Cms) / TNN / Updated: Aug 31, 2013, 04:34 IST

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MUMBAI: In a further indication of the rot in the country's healthcare system, a parliamentary panel has rapped the government for gross irregularities in drug trials (https://timesofindia.indiatimes.com/topic/drug-trials), under-reporting and lapses in monitoring serious adverse events and lethargy in safeguarding health, in studies on cervical cancer (https://timesofindia.indiatimes.com/topic/cancer) prevention vaccine by a US-based non-governmental agency. Charging the government for inaction, the parliamentary committee on health says in a report that the issue has been diluted with no accountability fixed on erring officials for serious violations committed in the studies which led to the death of hapless tribal children three years back.

Raising concern on the manner in which the US NGO, PATH (https://timesofindia.indiatimes.com/topic/path) (Programme for Appropriate Technology in Health) set up office in the country, the panel says it conducted clinical trials for HPV (https://timesofindia.indiatimes.com/topic/hpv) vaccines under the garb of "observational project" by violating all guidelines.

The trials were suspended following deaths of five girls in Andhra Pradesh, and two deaths in Gujarat in 2009-2010 after being administered the HPV vaccines. The vaccines

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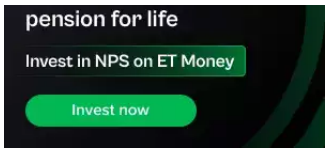

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were provided by two pharmaceutical companies – Merck and GlaxoSmithKline – through PATH, during studies carried out in collaboration with government agency, Indian Council of Medical Research (https://timesofindia.indiatimes.com/topic/indian-council-of-medical-research) and the states. The project was reportedly funded by Bill and Melinda Gates Foundation.

The sole aim of PATH, the 72nd report on Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) vaccine says, was to "promote the commercial interests'' of the manufacturers, who would have benefitted if it was successful in getting the HPV vaccine included in the government-run Universal Immunisation Programme.

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The report submitted in the Parliament on Friday comes at a time when the pharma industry has been complaining of inordinate government delays in approvals of drug trials involving human subjects.

Terming it "a serious breach of trust by any entity", and a "violation of human rights of these girl children who were mostly unaware of the implications'', the panel has asked the government to report the violations to international bodies like World Health Organisation and UNICEF. It has also asked the ministry of health to take up the matter through the ministry of external affairs with the US government so as to ensure appropriate action is taken against PATH.

The report has pulled up the drugs controller general as well as Indian Council of Medical Research. It says DCGI played a "questionable role'', and "remained a silent spectator, even when its own regulations were being violated", while "approvals of clinical trials, marketing

approvals and import licenses appear to be irregular".Though the issue was reported after the deaths in 2010, this report details the role of PATH, involvement of regulatory agencies like ICMR and DCGI, lapses in drug side-effects, conflict of interest and the various loop-holes in the system.

The panel says that ICMR instead of ensuring ethical standards in research studies, apparently acted at the behest of PATH in promoting the interests of HPV manufacturers, and that it should have taken the National Technical Advisory Group on Immunization (NTAGI), on board. The safety, efficacy and introduction of vaccines is handled by NTAGI.

Significantly, not only were the adverse events under-reported and not monitored during the studies, the committee noted that HPV vaccine as a possible, if not probable cause of suicidal ideation.

According to approvals given to the companies, vaccines were given to children irrespective of age in the case of Merck's Gardasil vaccine, while permission was given to use GSK's Cervarix vaccine in children (10-14 years), while clinical trials had been conducted on subjects in the age-group of 18-35 years. Thus the safety and well-being of subjects were completely jeopardized, the report adds.

The panel has sought further tightening of regulations, action against the wrong-doers, strict monitoring of serious adverse events during drug trials through an independent mechanism, and government agencies ICMR and DCGI to strictly adhere to regulations, guidelines and methodology like informed consent from subjects. The committee found glaring discrepancies in the informed consent taken from subjects who were given the vaccine.

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Elevate your career trajectory with University of Massachusetts Global's MBA program- tailored to offer you a strategic edge

SPOTLIGHT / Jun 28, 2024, 17:19 IST

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As technology takes over and businesses expand operations on a global scale, the skill set required for success needs to evolve. This makes it crucial for professionals to know how companies operate beyond local borders to make strategic decisions. With teams operating across diverse regions, the ability to productively collaborate and connect with individuals from diverse backgrounds is now a non-negotiable skill set for those aspiring to climb the career ladder.

So, how do professionals aiming to scale up the career ladder amp up their competency and prepare for the future? The answer lies in pursuing a Global MBA (https://international.umassglobal.edu/onlinemba?utm_source=timestoi&utm_medium=affiliate&utm_campaign=times_toi_article_spotlight).

For professionals looking to dive deep into larger business operations and elevate their professional trajectory, a Global MBA has a unique advantage. It offers a strategic blend of theoretical knowledge and practical insights, often exceeding the offerings of conventional MBA degrees. This makes it an ideal degree to understand the complexities of the global market and thrive in an interconnected business world.

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Recognizing this need for global perspectives in management, University of Massachusetts Global (UMass Global) offers a Master of Business Administration (MBA) program (https://international.umassglobal.edu/onlinemba?utm_source=timestoi&utm_medium=affiliate&utm_campaign=times_toi_article_spotlight). The program blends theory and practice of business administration so that professionals can mold themselves into hands-on leaders who can plan, execute, monitor, evaluate, and create value for global businesses. The program is specifically for mid to senior-level professionals looking for a global edge in their career trajectory, this 18-month program blends the flexibility of online learning with the practicality of real-world case studies.

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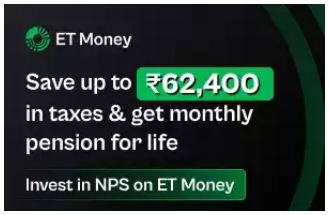
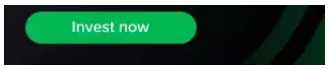
UMass Global's MBA program is tailored for today's professionals who are looking to scale up their careers and transform themselves into leaders. It follows an experiential learning model, enabling students to actively apply theoretical concepts in practical situations. The program curriculum has been designed keeping in mind global business dynamics, placing a strong emphasis on fostering leadership skills through immersive hands-on experiences.





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A diverse range of modules to transform young professionals into global leaders

UMass Global's Master of Business Administration (MBA) program (https://international.umassglobal.edu/onlinemba?utm_source=timestoi&utm_medium=affiliate&utm_campaign=times_toi_article_spotlight) features a range of program modules to push professionals toward breakthrough success in the business landscape. With modules such as economic analysis, data-driven decision-making, marketing management, and financial reporting allowing learners to gain theoretical insights along with practical application. Modules such as leadership and innovation, leadership and business operations, and conflict and negotiation help mold learners into global leaders with the most effective communication approaches. The capstone course, focusing on strategic business operations, provides a

comprehensive project-based approach to operational improvement, drawing on diverse perspectives and global challenges.

Why UMass Global?

If you aspire to become a global leader, the University of Massachusetts Global could be a strategic decision that elevates your career trajectory. As a private, nonprofit institution accredited by the WASC Senior College and University Commission, it comes with a 65-year legacy of helping working professionals upskill. The institution's credibility is further underscored by its accreditation and the fact that 91% of its alumni would recommend UMass Global to others. Further, pursuing an MBA from UMass Global also positions one for leadership roles and projects within both existing and new organizations. With this, the program gives way to professional development, so learners can chart their path toward global leadership.

Who is this program for?

UMass Global's MBA program is a transformative journey that provides learners with a comprehensive skill set to thrive in the dynamic professional landscape. For those with entrepreneurial aspirations, the program could also be the launchpad to gain the knowledge and skills needed to manage one's own business. It can particularly benefit the following set of professionals:

· Mid-career professionals who are looking to augment their business knowledge and activate advanced leadership skills.

· Business leaders who are aiming to enhance and sharpen their managerial expertise and are aspiring to transition

into C-suite roles.

To enhance the program, it integrates live sessions with industry experts where students can interact, ask questions, and gain insights from professionals. By eliminating the need for relocation, travel, and accommodation expenses associated with traditional classroom-based programs, UMass Global's MBA program ensures affordability. This, combined with the flexibility of online learning, makes it a practical and accessible choice for students aspiring to elevate their careers.

A look at the features of this program

UMass Global's MBA comes with distinctive features that set the program apart from conventional MBA degrees. By focussing on 360-degree academic and professional success, it offers learners with the following advantages:

· A renowned, WES-recognized* university degree from a global university that solidifies your credentials in the competitive business landscape.

· Practical knowledge and applicable skills with pre-recorded lectures, quizzes, projects, simulations, and assignments, ensuring practical knowledge and applicable skills.

· An MBA that stands on par with a master's degree obtained through traditional classroom training in the United States, ensuring the same level of academic rigor and excellence.

· Flexible and interactive online learning through a combination of pre-recorded lectures and live sessions with industry experts.

· Global opportunities to position yourself as a business changemaker with a global perspective and skills for diverse opportunities on an international scale.

· Access to the University of Massachusetts Global alumni network, which you can tap for better opportunities, resources, and a supportive community.

Program details:

Duration: 18 months

Program fee: ₹3,32,000 + GST

Eligibility: Indian student with a valid bachelor's degree with a 2.75 GPA (equivalent to more than 45%) or valid master's degree (no minimum GPA)

Tuition Fee benefit of INR 25,000 available till 3 July 2024

If you are looking to accelerate your career with a global MBA degree, UMass Global stands out as a strategic choice to start your journey. With a 65-year legacy in upskilling working professionals, this MBA program focuses on an experiential learning model and will go a long way towards helping you become an effective business leader in a competitive and diverse environment.

To learn more about the program, click here (https://international.umassglobal.edu/onlinemba?utm_source=timestoi&utm_medium=affiliate&utm_campaign=times_toi_article_spotlight).

*WES evaluates all programs to a US equivalency. The University of Massachusetts Global online MBA program,

based in the U.S. and offered by a U.S. university, has successfully met all the requirements and does not need additional WES evaluation, saving students valuable time and money.

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Hopes of govt-opposition cooperation sinks with Rajya Sabha spat

Updated: Aug 31, 2013, 04:27 IST

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Hopes of a non-partisan political consensus over the economic crisis died a quick death in Rajya Sabha on Friday with a combative PM Manmohan Singh taking BJP head on over

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NEW DELHI: Hopes of a non-partisan political consensus over the economic crisis died a quick death in Rajya Sabha (https://timesofindia.indiatimes.com/topic/rajya-sabha) on Friday with a combative Prime Minister Manmohan Singh (https://timesofindia.indiatimes.com/topic/manmohan-singh) taking BJP head on over charges of corruption leveled against his government.

Replying to leader of opposition Arun Jaitley (https://timesofindia.indiatimes.com/topic/arun-jaitley)'s pungent observation that the PM's appeal for a non-partisan approach reflected the government's penchant to being democratic only when in distress, Singh hit back saying the main opposition remained unreconciled to being out of power.

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In a response bordering on an outburst, he sought to blame BJP for what he said was its role in generating an impression that India was no longer an investor friendly destination by repeated disruption of Parliament. Singh said nowhere else did the main opposition party rush to the well of the House accusing the PM of being corrupt while emphasizing that building consensus was not just the responsibility of the government but also involved the opposition.

Jaitley's suggestion that Singh's legacy as PM was at risk and he may not end his tenure in office being hailed as a reformer as when he was finance minister also seemed to hit home. "The choice is between prudence and populism... The legacy you will leave behind is, after me the deluge," he said.

The PM's aggressive mood was also evident when he was asked by an opposition MP about issues he would take up

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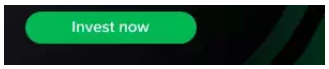

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at the upcoming G20 summit in Russia.

"Whatever some members of the opposition may think about me, I command certain status and respect in the G20 council," Singh shot back, before he went on to explain that he would emphasize how decisions taken by the developed world are impacting developing countries in an interdependent world.

When Singh spoke of the opposition's unprecedented disruption of Parliament, Jaitley immediately retorted saying the opposition too had not heard of any democracy where monetary inducements were resorted to win a vote of confidence.

This led to bedlam as Congress's Mani Shankar Aiyar demanding that Jaitley be expelled from the House. He said Jaitley was a liar which enraged BJP MPs.

As opposition accused him of delivering a political speech, Singh ensured that no slogan or barb went unanswered, not even one on missing 'Coalgate' files to which he said he was not the custodian of coal files. Undeterred, AIADMK's V Maitreyan yelled that the PM was the custodian of the country.

"Parliament is the supreme body in the country and is not allowed to function session after session. I am glad the principal opposition recognizes the need for consensus in the House… but it takes two hands to clap," said Singh.

This was after Jaitley said while there was a need for a larger consensus on economic issues, the government's track record made this difficult. "It emerges out of political environment, which is broken and fractured by the government," he said.

Jaitley said corruption was also a key reason for the present state of affairs as telecom licences were cancelled and coal imports rose in the wake of Coalgate.

Singh went on to appeal to the main opposition and other political parties to work with the government on reforms which he described as important for improving the economic situation, including pension and insurance, subsidies and bureaucratic red tape. "These are not low lying fruits. States also have to agree to GST," he said.

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Samajwadi Party asks whether Yasin Bhatkal arrested for his religion

TNN / Aug 31, 2013, 04:21 IST

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Samajwadi Party raised doubts if Yasin Bhatkal was actually arrested because of his crime, stirring a controversy over the prize catch of the Indian Mujahideen commander by

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EW DELHI: Samajwadi Party (https://timesofindia.indiatimes.com/topic/samajwadi-party) raised doubts if Yasin Bhatkal (https://timesofindia.indiatimes.com/topic/yasin-bhatkal) was actually arrested because of his crime, stirring a controversy over the prize catch of the Indian Mujahideen (https://timesofindia.indiatimes.com/topic/indian-mujahideen) commander by suggesting it could be a case of Muslim persecution.

SP leader Kamal Farooqui (https://timesofindia.indiatimes.com/topic/kamal-farooqui) said on Friday, "Police should ascertain whether Yasin Bhatkal's arrest is based on crime or religion."

The remark echoed the suspicion that has regularly been aired about arrest of terrorists, with police being the butt of attack for "victimizing" Muslim youth.

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Farooqui, who routinely appears on television as a Samajwadi representative, said, "There have been instances in the past when cops have branded individuals as top terrorists, but have failed to prove charges against them. There have been cases when arrests have been made solely on basis of religion. I appeal that all facts should be probed before taking action against him."

While Bhatkal's arrest appeared above board because of his alleged involvement in several blasts, the Samjawadi leader's comment was seen as part of his party's minority politics, treated as a key weapon ahead of elections.

The Akhilesh Yadav government in Lucknow had moved court for release of many terror accused but the move fell through because courts took a strong stance. Many felt Farooqui's comment was aimed at reinserting the charge

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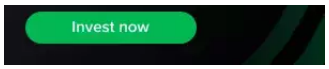

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of religious stereotyping against the Centre to put the Congress on the back foot.

BJP was quick to slam Farooqui. "It is deeply unfortunate that he is using religion to compromise the security of the country," BJP spokesman Ravi Shankar Prasad said.

Farooqui's statement is unlikely to go down without notice in BSP or Congress, worried as they are about repeated attempts to stoke religious polarization. When VHP made a bid to take out a yatra in Ayodhya to press for Ram temple last week, these parties alleged that SP and the saffron camp had joined hands to unleash religious sentiments ahead of polls.

The SP comment on Bhatkal is seen in the same vein, aimed at inviting a "communal" reaction that would serve the same purpose.

In the backdrop of religious clashes that returned under the Samajwadi regime in UP after the peace of five years under BSP, political leaders from the non-SP stable think attempts are on to squeeze out parties that do not perform well in a polarized atmosphere.

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